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Dated: October 17, 2006

Signature:

(John Barretto)

Docket No.: TNA-005.04  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Re Patent Application of:  
Jin-An Jiao *et al.*

Application No.: 10/618,338

Confirmation No.: 8452

Filed: July 11, 2003

Art Unit: 1646

For: ANTIBODIES FOR INHIBITING BLOOD  
COAGULATION AND METHODS OF USE  
THEREOF

Examiner: X. Xie

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

**UNDER CFR 1.97(c)(2)**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

Applicants have listed dates of publication on the attached PTO-1449 for the cited documents based on information presently available to the undersigned. However, the listed

publication dates should not be construed that the information in the cited documents was actually published or otherwise publicly available on the date indicated.

This submission does not represent that a search has been made or that no better art exists. Nor does it constitute an admission that each or all of the listed documents are material or constitute "prior art." Further, if the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Moreover, the Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

It is submitted that the Supplemental Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Please charge our Deposit Account No. 06-1448 in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 06-1448, under Order No. TNA-00504. A duplicate copy of this paper is enclosed.

Dated: October 17, 2006

Respectfully submitted,

By 

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PTO/SB/08a/b (07-06)

Approved for use through 09/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/618,338-Conf. #8452	
			Filing Date	July 11, 2003	
			First Named Inventor	Jin-An Jiao	
			Art Unit	1646	
			Examiner Name	X. Xie	
Sheet	1	of	4	Attorney Docket Number	TNA-00504

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA*	US-20020025508-A1	02-28-2002	Fechteler et al.	
	AB*	US-20030087372-A1	05-08-2003	DelaCruz et al.	
	AC*	US-20030119075-A1	03-09-2004	Kirchhofer et al.	
	AD*	US-20030176664-A1	09-18-2003	Jiao et al.	
	AE*	US-4,644,055	02-17-1987	Kettner et al.	
	AF*	US-4,816,567	03-28-1989	Cabilly et al.	
	AG*	US-5,122,458	06-16-1992	Post et al.	
	AH*	US-5,168,062	12-01-1992	Stinski	
	AI*	US-5,171,662	12-15-1992	Sharma	
	AJ*	US-5,225,539	07-06-1993	Winter et al.	
	AK*	US-5,385,839	01-31-1995	Stinski	
	AL*	US-5,530,101	06-25-1996	Queen et al.	
	AM*	US-5,534,254	07/1996	Huston et al.	
	AN*	US-5,766,886	06-16-1998	Studnicka et al.	
	AO*	US-5,861,267	01-19-1999	Su	
	AP*	US-5,879,677	03-09-1999	del Zoppo	
	AQ*	US-5,889,157	03-30-1999	Pastan et al.	
	AR*	US-5,958,713	09-28-1999	Thastrup et al.	
	AS*	US-5,985,279	11-16-1999	Waldmann et al.	
	AT*	US-5,997,867	12-07-1999	Waldmann et al.	
	AU*	US-6,001,978	12-14-1999	Edgington et al.	
	AV*	US-6,054,297	04-25-2000	Carter et al.	
	AW*	US-6,117,639	09-12-2000	Germann et al.	
	AX*	US-6,245,884	06-12-2001	Hook	
	AY*	US-6,331,415	12-18-2001	Cabilly et al.	
	AZ*	US-6,333,167	12-25-2001	Quinet et al.	
	AA1*	US-6,555,319-A1	04-29-2003	Wong et al.	
	AB1*	US-6,593,291	07-15-2003	Green et al.	
	AC1*	US-6,610,293	08-26-2003	Fischer et al.	
	AD1*	US-6,677,436	01-13-2004	Sato et al.	
	AE1*	US-6,703,494-A1	03-09-2004	Kirchhofer et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	EP 1 069 185	01-17-2001			
	BB	WO 89/12463	12-28-1989			
	BC	WO 98/40408	09-17-1998			
	BD	WO 03/029295	04-10-2003			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				Application Number	10/618,338-Conf. #8452
				Filing Date	July 11, 2003
				First Named Inventor	Jin-An Jiao
				Art Unit	1646
				Examiner Name	X. Xie
Sheet	2	of	4	Attorney Docket Number	TNA-00504

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	CA	Benhar et al., "Rapid Humanization of the Fv of Monoclonal Antibody B3 by Using Framework Exchange of the Recombinant Immunotoxin B3(Fv)-PE38," Proc. Natl. Acad. Sci. USA, 91:12051-12055 (1994)		
	CB	Booy et al., "Monoclonal and bispecific antibodies as novel therapeutics," Arch. Immunol. Ther. Exp., 54:85-101 (2006)		
	CC	Boulianne et al., "Production of functional chimaeric mouse/human antibody," Nature, 312:643-646 (1984)		
	CD	Bruggemann et al., "The Immunogenicity of Chimeric Antibodies," J. Exp. Med. 170:2153-2157 (1989)		
	CE	Carter et al., "Humanization of an anti-p185HER2 antibody for human cancer therapy," Proc. Natl. Acad. Sci. USA, 89:4285-4289 (1992)		
	CF	Casipit et al., "Improving the binding affinity of an antibody using molecular modeling and sit directed mutagenesis," Protein Science, 7:1671-1680 (1998)		
	CG	Chothia et al., "The outline structure of the T-Cell $\alpha\beta$ receptor," The EMBO Journal, 7(12):3745-3755 (1988)		
	CH	Co et al., "Humanized antibodies for antiviral therapy," Proc. Natl. Acad. Sci. USA, 88:2869-2873 (1991)		
	CI	Couto et al., "Anti-BA46 Monoclonal Antibody Mc3: Humanization Using a Novel Positional Consensus and In Vivo and In Vitro Characterization," Cancer Research, 55:1717-1722 (1995)		
	CJ	Couto et al., "Designing Human Consensus Antibodies with Minimal Positional Templates," Cancer Research (Suppl.) 55:5973s-5977s (1995)		
	CK	Faber et al., "A Novel Method to Determine the Topology of Peroxisomal Membrane Proteins in Vivo Using the Tobacco Etch Virus Protease," The Journal of Biological Chemistry, 276(39):36501-36507 (2001)		
	CL	Foote et al., "Antibody Framework Residues Affecting the Conformation of the Hypervariable Loops," J. Mol. Biol., 224:487-499 (1992)		
	CM	Gorman et al., "Reshaping a therapeutic CD4 Antibody," Proc. Natl. Acad. Sci. USA, 88:4181-4185 (1991)		
	CN	Gregoire et al., "Engineered secreted T-cell receptor $\alpha\beta$ heterodimers," Proc. Natl. Acad. Sci. USA, 88:8077-8081 (1991)		
	CO	Griffiths et al., "Human anti-self antibodies with high specificity from phage display libraries," The EMBO Journal, 12(2):725-734 (1993)		
	CP	Hanes et al., "Picomolar affinity antibodies from a fully synthetic naive library selected and evolved by ribosome display," Nature Biotechnology, 18:1287-1292 (2000)		
	CQ	Jager et al., "Current Status of Cancer Immunodetection with Radiolabeled Human Monoclonal Antibodies, Seminars in Nuclear Medicine, Vol. XXIII, No. 2, 165-179 (1993)		
	CR	Janeway et al., Immunobiology, third edition, Garland Press, pp. 3:7-3:11 (1997)		
	CS	Kao et al., "Chimeric Antibodies with Anti-Dextran-Derived Complementarity-Determining Regions and Anti-p-Azophenylarsonate-Derived Framework Regions," The Journal of Immunology, 151:1968-1979 (1993)		
	CT	Knappik et al., "Fully Synthetic Human Combinatorial Antibody Libraries (HuCAL) based on Modular Consensus Frameworks and CDRs Randomized with Trinucleotides," J. Mol. Biol., 296:57-86 (2000)		
	CU	Leong et al., "Adapting pharmacokinetic properties of a humanized anti-interleukin-8 antibody for therapeutic applications using site-specific pegylation," Cytokine, 16(3):106-119 (2001)		

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Sheet	3	of	4	Attorney Docket Number	TNA-00504

CV	LoBuglio et al., "Mouse/human chimeric monoclonal antibody in man: Kinetics and immune response," Proc. Natl. Acad. Sci. USA, 86:4220-4224 (1989)	
CW	Mateo et al., "Humanization of a mouse monoclonal antibody that blocks the epidermal growth factor receptor: recovery of antagonistic activity," Immunotechnology, 3:71-81 (1997)	
CX	Morrison et al., "Chimeric human antibody molecules: Mouse antigen-binding domains with human constant region domains," Proc. Natl. Acad. Sci. USA, 81:6851-6855 (1984)	
CY	Morrison et al., "Genetically Engineered Antibody Molecules," Advances in Immunology, 44:65-93	
CZ	Novotny et al., "A soluble, single-chain T-cell receptor fragment endowed with antigen-combining properties," Proc. Natl. Acad. Sci. USA, 88:8646-8650 (1991)	
CA1	Onda et al., "A phage display system for detection of T cell receptor-antigen interactions," Molecular Immunology, 32(17-18):1387-1397 (1995)	
CB1	Owens et al., "The Generic Engineering of Monoclonal Antibodies," Journal of Immunological Methods, 168:149-165 (1994)	
CC1	Padlan, "A possible procedure for reducing the immunogenicity of antibody variable domains while preserving their ligand-binding properties," Mol. Immun., 28(4/5):489-498 (1991)	
CD1	Padlan, "Anatomy of the antibody molecule," Molecular Immunology, 31(3):169-217 (1994)	
CE1	Padlan, "On the Nature of Antibody Combining Sites: Unusual Structural Features That May Confer on These Sites an Enhanced Capacity for Binding Ligands," Proteins, 7:112-124 (1990)	
CF1	Queen et al., "A humanized antibody that binds to the interleukin 2 receptor," Proc. Natl. Acad. Sci. USA, 86:10029-10033 (1989)	
CG1	Queen et al., "Cell-Type Specific Regulation of a k Immunoglobulin Gene by Promoter and Enhancer Elements," Immunological Reviews, 89:49-68 (1986)	
CH1	Rangel-Frausto, M. Sigfrido, "Sepsis: Still Going Strong," Archives of Medical Research, 36:672-681 (2005)	
CI1	Reichart, "Monoclonal antibodies in the clinic," Nature Biotechnology, 19:819-822 (2001)	
CJ1	Reichmann et al., "Reshaping human antibodies for therapy," Nature, 332:323-327 (1988)	
CK1	Robertson, "Genentech awarded critical antibody patent," Nature Biotechnology, 20:108 (2002)	
CL1	Roguska et al., "A comparison of two murine monoclonal antibodies humanized by CDR-grafting and variable domain resurfacing," Protein Engineering, 9(10):895-904 (1996)	
CM1	Roguska et al., "Humanization of murine monoclonal antibodies through variable domain resurfacing," Proc. Natl. Acad. Sci. USA, 91:969-973 (1994)	
CN1	Rudikoff et al., "Single amino acid substitution altering antigen-binding specificity," Proc. Natl. Acad. Sci. USA, 79:1979-1983 (1982)	
CO1	Saldanha et al., "A single backmutation in the human kIV framework of a previously unsuccessfully humanized antibody restores the binding activity and increases the secretion in cos cells," Molecular Immunology, 36:709-719 (1999)	
CP1	Shearman et al., "Construction, expression and characterization of humanized antibodies directed against the human $\alpha/\beta$ T cell receptor," The Journal of Immunology, 147:4366-4373 (1991)	
CQ1	Tan et al., "Superhumanized Antibodies: Reduction of Immunogenic Potential by Complementarity-Determining Region Grafting with Human Germline Sequences: Application to an Anti-CD28," The Journal of Immunology, 169:1119-1125 (2002)	
CR1	Taylor et al., "Protein C Prevents the Coagulopathic and Lethal Effects of Escherichia coli Infusion in the Baboon," J. Clin. Invest., 79:918-925 (1987)	
CS1	Taylor, F.B., "Staging of the pathophysiologic responses of the primate microvasculature to Escherichia coli and endotoxin: examination of the elements of the compensated response and their links to the corresponding uncompensated lethal variants," Crit. Care Med., 29(&):S78-89 (2001)	
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				Examiner Name	X. Xie
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	CT1	Tempest et al., "Reshaping a human monoclonal antibody to inhibit human respiratory syncytial virus infection in vivo," Bio/Technology, 9:266-271 (1991)	
	CU1	Teng et al., "Construction and testing of mouse-human heteromyelomas for human monoclonal antibody production," Proc. Natl. Acad. Sci. USA, 80:7308-7312 (1983)	
	CV1	Tomizuka et al., "Double trans-chromosomal mice: Maintenance of two individual human chromosome fragments containing Ig heavy and k lock and expression of fully human antibodies," PNAS, 97(2):722-727 (2000)	
	CW1	Vaughan et al., "Human Antibodies with Sub-nanomolar Affinities Isolated from a Large Non-immunized Phage Display Library," Nature Biotechnology, 14:309-314 (1996)	
	CX1	Verhoeyen et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity," Science, 239:1534-1536 (1988)	
	CY1	Ward, E. S., "Expression and Secretion of T-Cell Receptor V $\alpha$ and V $\beta$ Domains using Escherichia coli as a Host," Scand. J. Immunol., 34:215-220 (1991)	
	CZ1	Watson et al., Molecular Biology of the Gene, fourth edition, The Benjamin/Cummings Publishing Company, Inc., p. 840 (1987)	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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